DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sun Nuclear Corporation
% Mr. James Luker
Regulatory Affairs Consultant
2640 Nobility Avenue
MELBOURNE FL 32934

November 20, 2015

Re: K142617
Trade/Device Name: ArcCHECK, Model 1220
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 15, 2015
Received: November 17, 2015

Dear Mr. Luker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142617

Device Name
ArcCHECK, Model 1220

Indications for Use *(Describe)*
ArcCHECK, Model 1220 is a three-dimensional (3D) ionizing radiation measurement device intended for radiotherapy quality assurance.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Provided in accordance with 21 CFR 807.92 (c)

1 General Provisions

Date Prepared:

November 17, 2015

Submitted by:

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Melbourne, FL 32940
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Contact Person:

James Luker
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Ph: 321-259-6862 extension 2428

Common Name:

Dosimetric Quality Assurance for Patient Specific Radiation Treatment

Proprietary Names:

Model 1220 ArcCHECK

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Name: Medical charged-particle radiation therapy system
Product code: IYE

Class II

Predicate Device(s):

Model Name:	Model 1220 ArcCHECK
Common Name:	Dosimetric Quality Assurance for Patient Specific Radiation Treatment
510(k) #	K131466
Manufacturer:	Sun Nuclear Corporation.
Submitted:	May 21, 2013

2 Description and Use:

ArcCHECK, Model 1220 is a three dimensional diode sensor used for ionizing radiation measurement for radiotherapy quality assurance. The cylindrical diode array is embedded in a cylindrical plastic phantom that allows for dosimetry measurements to be made from all gantry angles as the therapy beam rotates about the diode array.

The provided GUI 'SNC Patient' software application installed on the user's computer and connected to the Model 1220 ArcCHECK by an 8 pin DIN cable, includes the following functions:

- Array and dose calibration.
- Measurement and display of the spatial distribution of the dose resulting from delivery of a radiation treatment plan.
- Save measurements.
- Import treatment plan dose map in the phantom and compares with the measurement dose points.
- Compare the measured and planned dose distribution using the analysis methods of gamma or dose difference and distance to agreement (DTA) with user specified analysis criteria.
- Report of the analysis including a percent pass rate.
- Perform quality assurance (QA) on the planned versus delivered multi leaf collimator (MLC) pattern as a function of time. The MLC QA is capable of detecting an error of 5mm or greater in the planned position of an MLC leaf.

This submission introduces a 'primary' software modification to the cleared Model 1220 ArcCHECK device (K131466). Sun Nuclear intends to introduce a software feature which allows for the user to perform quality assurance (QA) on the planned versus delivered Multi Leaf Collimator (MLC) pattern. The MLC QA is capable of detecting an error of 5mm or greater in the planned position of an MLC leaf. This 'primary' modification which is believed to affect the indications for use, but not the intended use, is the subject of this premarket notification.

3 Intended Use Statement:

ArcCHECK, Model 1220 is a three-dimensional (3D) ionizing radiation measurement device intended for radiotherapy quality assurance.

4 Technological Characteristics

The primary technological characteristics of ArcCHECK, Model 1220 is the high spatial resolution of the diode detector with an array size and a detector density that enables measurement of dose distributions that have high dose gradients found in radiotherapy deliveries. The spatial resolution of the diode detector results in very little dose volume averaging over the high dose gradient regions in the plan.

The ArcCHECK serves as a 3D Phantom with the detectors located on a 3D cylindrical surface embedded at a radiological depth of 3.3g/cm^2.

5 Performance Data and Comparison with Predicate

ArcCHECK, Model 1220 has been tested using appropriate bench testing methods. We have determined the software to be of 'Major Level of Concern' and have performed appropriate verification and validation testing.

Test results of the modified device have demonstrated that the device performs within its design specifications and equivalently to the predicate K131466 ArcCHECK device.

6 Summary

ArcCHECK, Model 1220 is believed to be substantially equivalent to the predicate ArcCHECK device due to the similarities in function, technology, and performance. The intended use, performance testing, safety and effectiveness reviews demonstrate that ArcCHECK, Model 1220 is as safe, as effective, and performs as well as the predicate device. The changes to the predicate device described within this submission are not thought to not raise new types of safety or effectiveness questions.